

REMARKS

I. Introduction

These amendments and remarks are being filed in response to the Office Action dated April 16, 2008.

Claims 1-24 are pending in this application. Claims 7 and 10-15 were withdrawn by the Examiner following a Restriction Requirement. Claims 3-5 and 16-24 were rejected under 35 U.S.C. § 112, second paragraph; claims 1, 2, 4-6, 8, 9, 16-21 and 23 were rejected under 35 U.S.C. § 102(b) and claims 1, 3, 22 and 24 were rejected under 35 U.S.C. § 103(a).

Claims 3-5 have been amended to clarify the claim language.

No new matter has been added.

For the following reasons, Applicants respectfully submit that the claims should be allowed and the application passed to issue.

II. Claim Rejections Under 35 U.S.C. § 112, second paragraph

Claims 3-5 and 16-24 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. Applicants respectfully disagree with the rejection; however, in the interest of expediting prosecution, claims 3-5 have been amended to delete the phrase “or a derivative thereof,” thereby obviating the rejection. Derivates are now not recited in dependent claims 3-5, but are covered by claims 1-2.

III. Claim Rejections Under 35 U.S.C. § 102(b)

Claims 1, 2, 4-6, 8, 9, 16-21 and 23 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Hennink WO 98/00170. Applicants respectfully disagree and reconsideration is respectfully solicited

Claim 1, recites, “[a] polymeric material comprising a smart segment and a biodegradable segment, wherein the biodegradable segment includes a hydrophobic segment and a hydrophilic segment.”

Anticipation under 35 U.S.C. § 102 requires that “each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed Cir. 1987). At a minimum, the cited prior art does not disclose (expressly or inherently), “[a] polymeric material comprising a *smart segment* and a biodegradable segment, wherein the biodegradable segment includes a hydrophobic segment and a hydrophilic segment.” [Emphasis added].

The Office Action, at page 3 alleges that Hennink describes hydrolysable hydrogels having a smart segment, HEMA. However, Hennink’s polymers do not contain a *smart* segment, as recited in claim 1. The HEMA itself is not a smart polymer. A person having ordinary skill in the art would recognize, that smart polymers are materials which respond to small changes in their environment with dramatic changes in their physical properties.

In fact, the term “smart segment,” is defined in the instant specification in paragraph 27, on page 6 in the following manner,

“the smart segment is responsive to an external stimulus, such as a chemical, biological, or physical stimulus, and sharply changes at least one of its physical properties in response to the stimulus. For example, bioresponsive polymers respond to physical, chemical, or biological stimuli, such as temperature, pH,

ionic strength, magnetic field, electrical field, pressure, light, enzyme, receptor, glucose, etc. by altering their swelling behavior, permeability or mechanical strength.”

As such, a person having ordinary skill in the art would not consider HEMA, (Hydroxyethylmethacrylate), to be a smart polymer, as it merely absorbs waters and swells, and it does not fall into the definition of a smart segment as recited in the specification.

As such, Hennink fails to disclose all of the elements of claim 1.

Accordingly, claim 1 is allowable over the cited prior art reference.

Furthermore, claims 2-6, 8, 9 and 16-24 depend from and further define the subject matter of claim 1 and therefore are also allowable.

IV. Claim Rejections Under 35 U.S.C. § 103(a)

Claims 1, 3, 22 and 24 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Hennink in view of Marchant, U.S. 2002/0068087. Applicant respectfully traverse this rejection.

On page 4 of the Office Action, the Examiner concedes that Hennink does not disclose that, “the smart segment comprises poly(N-isopropylacrylamide), poly(N-alkylacrylamide), poly(N-n-propylacrylamide), poly(N-isopropylmethacrylamide), poly(ethylene oxide)-poly(propylene oxide)-poly(ethylene oxide), elastin-like polypeptides,” as recited in claim 3.

However, the Examiner alleges that Marchant teaches a composition containing poly N-isopropylacrylamide and then concludes that it would have been obvious to use poly N-isopropylacrylamide in place of the HEMA in Hennink.

In order to establish a *prima facie* obviousness rejection under 35 U.S.C. § 103(a), basic criteria must be met. First, there must be some suggestion or motivation, either in the references

themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must not be based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Further, "rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *In re Kahn*, 441 F. 3d 977, 988 (Fed. Cir. 2006).

At a minimum, the cited prior art does not disclose (expressly or inherently), "[a] polymeric material comprising a smart segment and a biodegradable segment, wherein the biodegradable segment includes a hydrophobic segment and a hydrophilic segment," as recited in claim 1.

As discussed above, in reference to the rejection under 35 U.S.C. § 102(b), Hennink does not teach or suggest the use of a smart segment in "a polymeric material comprising a smart segment and a biodegradable segment, wherein the biodegradable segment includes a hydrophobic segment and a hydrophilic segment."

Moreover, Marchant fails to cure the deficiencies of Hennink because Marchant also does not teach or suggest the use of smart segments in hydrogels comprising "[a] smart segment and a biodegradable segment, wherein the biodegradable segment includes a hydrophobic segment and a hydrophilic segment," as recited in claim 1.

Furthermore, Marchant only refers to poly N-isopropylacrylamide in the background section of the specification. The Marchant publication is directed to bioadhesive hydrogels.

In fact, Marchant refers to hydrogel of poly N-isopropylacrylamide in the context of poly N-isopropylacrylamide not having bioadhesive properties, the concern of the Marchant publication.

As such, it would not be obvious to one having ordinary skill in the art to replace the HEMA of Hennink with poly N-isopropylacrylamide as discussed in Marchant, because Marchant teaches away from using poly N-isopropylacrylamide.

Finally, neither cited prior art references teaches all the elements of the claims, either alone or in combination. In particular, none of the cited prior art references teaches or suggests “[a] smart segment and a biodegradable segment, wherein the biodegradable segment includes a hydrophobic segment and a hydrophilic segment,” as recited in claim 1 .

Thus, there is no articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.

V. Conclusion

In view of the above amendments and remarks, Applicants submit that this application should be allowed and the case passed to issue. If there are any questions regarding this Amendment or the application in general, a telephone call to the undersigned would be appreciated to expedite the prosecution of the application.

To the extent necessary, a petition for an extension of time under 37 C.F.R. 1.136 is hereby made. Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

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A handwritten signature in black ink, appearing to read 'Amer S. Ahmed', is written over the firm name.

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